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**PATENT**

Atty. Docket No.  
**AR02164USADIV2**

CN 27777

Date: Feb 10, 2004 By: *Lois E. Miller*  
Lois E. Miller

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): David E. EDGREN et al.

Serial No.: 10/696,217

Filed: October 28, 2003

For: ANTIDEPRESSANT DOSAGE  
FORM

Group Art Unit: to be assigned

Examiner: to be assigned

**INFORMATION DISCLOSURE  
STATEMENT**

Honorable Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the

mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☒ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☒ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750.

Respectfully submitted,

  
Attorney for Applicants

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Substitute for form 1449A-PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 3

Application Number	10/696,217
Filing Date	October 28, 2003
First Named Inventor	David E. EDGREN
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	AR02164USADIV2

### U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
	AA	2,799,241		Wurster	07/16/1957	
	AB	3,133,132		Loeb et al.	05/12/1964	
	AC	3,173,876		Zobrist	03/16/1965	
	AD	3,276,586		Rosaen	10/04/1966	
	AE	3,541,005		Strathmann et al.	11/17/1970	
	AF	3,541,006		Bixler et al.	11/17/1970	
	AG	3,546,142		Michaels et al.	12/08/1970	
	AH	3,589,122		Zaffaroni	08/10/1971	
	AI	3,589,123		Zaffaroni	08/10/1971	
	AJ	3,845,770		Theeuwes et al.	11/05/1974	
	AK	3,916,899		Theeuwes et al.	11/04/1975	
	AL	4,063,064		Saunders et al.	12/13/1977	
	AM	4,088,864		Theeuwes et al.	05/09/1978	
	AN	4,111,201		Theeuwes et al.	09/05/1978	
	AO	4,160,020		Ayer et al.	07/03/1979	
	AP	4,200,098		Ayer et al.	04/29/1980	
	AQ	4,285,987		Ayer et al.	08/25/1981	
	AR	4,327,725		Cortese et al.	05/04/1982	
	AS	4,535,189		Husbands et al.	08/13/1985	
	AT	4,611,078		Husbands et al.	09/09/1986	
	AU	4,612,008		Wong et al.	09/16/1986	
	AV	4,761,501		Husbands et al.	08/02/1988	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 2 of 3

Application Number	10/696,217
Filing Date	October 28, 2003
First Named Inventor	David E. EDGREN
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
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Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
	AW	4,765,989		Wong et al.	08/23/1988	
	AX	4,783,337		Wong et al.	11/08/1988	
	AY	4,842,867		Ayer et al.	06/27/1989	
	AZ	4,863,744		Urquhart et al.	09/05/1989	
	BA	4,946,687		Ayer et al.	08/07/1990	
	BB	4,948,592		Ayer et al.	08/14/1990	
	BC	4,950,486		Ayer et al.	08/21/1990	
	BD	4,966,769		Guittard et al.	10/30/1990	
	BE	5,190,765		Jao et al.	03/02/1993	
	BF	6,440,457	B1	Edgren et al.	08/27/2002	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
	BG	EP	0 112 669	A2	American Home Products	07/04/1984		

Examiner Signature		Date Considered	
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 3 of 3

Application Number	10/696,217
Filing Date	October 28, 2003
First Named Inventor	David E. EDGREN
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	AR02164USADIV2

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published	T <sup>2</sup>
	BH	Louis F. Fabre & H. Paul Putman, "An ascending single-dose tolerance study of WY-45,030, A bicyclic antidepressant, in healthy men," <u>Current Therapeutic Research</u> , 42(5):901-909, November 1987.	
	BI	Alvin Felmeister, "Powders," <u>Remington's Pharmaceutical Sciences</u> , 14 <sup>th</sup> Edition, Ch 86 & 87, pp. 1626-1648, Mack Publishing Co., 1970.	
	BJ	Goodman & Gilman, <u>The Pharmacological Basis of Therapeutics</u> , 4 <sup>th</sup> Ed., Page 182, Macmillan Publishing Co., New York, 1970.	
	BK	Goodman & Gilman, <u>The Pharmacological Basis of Therapeutics</u> , 7 <sup>th</sup> Ed., Page 7, Macmillan Publishing Co., New York, 1985.	
	BL	Goodman & Gilman, <u>The Pharmacological Basis of Therapeutics</u> , 8 <sup>th</sup> Ed., Pages 407 & 411, Pergamon Press, New York, 1990.	
	BM	P. Grafton, "General principles for designing with plastics," <u>Modern Plastics Encyclopedia</u> , 46:62-71, 1969.	
	BN	Robert E. King, "Tablets, Capsules, and Pills," <u>Remington's Pharmaceutical Sciences</u> , 14 <sup>th</sup> Edition, Ch. 87, pp. 1649-1680, Mack Publishing Co., 1970.	
	BO	Mark A. Longer & Joseph R. Robinson, "Sustained-Release Drug Delivery Systems," <u>Remington's Pharmaceutical Sciences</u> , 18 <sup>th</sup> Edition, Ch 91, pp. 1676-1686, Mack Publishing Co., 1990.	
	BP	<u>The Merck Index</u> , 11 Ed., page 1365 & MISC-107, 1989. "Sodium Nitrate"	
	BQ	<u>The Merck Index Online</u> , Merck & Co. 1996, 1997. "10079 Monograph Name: Venlafaxine"	
	BR	Scott & Roff, <u>Handbook of Common Polymers</u> , CRC Press., Cleveland Ohio, 1971.	
	BS	Dale E. Wurster, "Air-Suspension Technique of Coating Drug Particles", <u>J. Am. Pharm. Assoc.</u> , 48(8):451-454, August 1959	
	BT	Dale E. Wurster, "Preparation of Compressed Tablet Granulations by the Air-Suspension Technique II", <u>J. Am. Pharm. Assoc.</u> , 49(2):82-84, February 1960.	

Examiner Signature		Date Considered	
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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. <sup>6</sup> If possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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